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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,326	08/28/2003	Keith A. Hruska	JJJ-P01-599	6882

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,326	HRUSKA ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions—Main Groups

I. Claims 1, 3, 5, 12, 14, 16, 18-40 (in part), 41, 43-48 (in part), 49-52, 53 (in part), 55 (in part) are drawn to methods of administering an OP/BMP morphogen (or inducer or agonist thereof), and an angiotensin-converting enzyme inhibitor (ACEI), classified in part in class 514, subclass 2.

II. Claims 2, 4, 6, 13, 15, 17, 18-40 (in part), 42, 43-48 (in part), 54 (in part) are drawn to are drawn to methods of administering an OP/BMP morphogen (or inducer or agonist thereof), and an angiotensin II receptor antagonist (AIIRA), classified in part in class 514, subclass 2.

III. Claims 7, 9-11 (in part), 18-32 (in part), 46-47 (in part) 53-55 (in part) are drawn to methods of stem cell therapy comprising introducing renal mesenchymal progenitor cells pre-treated with an ACEI and an OP/BMP morphogen (or inducer or agonist thereof), classified in class 424, subclass 93.1.

IV. Claims 8, 9-11 (in part), 18-32 (in part), 46-47 (in part) 53-55 (in part) are drawn to methods of stem cell therapy comprising introducing renal mesenchymal progenitor cells pre-treated with an AIIRA and an OP/BMP morphogen (or inducer or agonist thereof), classified in class 424, subclass 93.1.

V. Claim 56, 58, 60-65 (in part), 66, 68 (in part) are drawn to pharmaceutical compositions comprising an ACE inhibitor and an OP/BMP morphogen, classified in class 514, subclass 2.

VI. Claims 57, 59, 60-65 (in part), 67, 68 (in part) are drawn to pharmaceutical compositions comprising an AIIRA and an OP/BMP morphogen, classified in class 514, subclass 2.

Inventions I and II-IV, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group I is drawn to methods of administering an OP/BMP morphogen (or inducer or agonist thereof), and an ***ACEI***, whereas Group II is drawn to methods of administering an OP/BMP morphogen (or inducer or agonist thereof), and an ***AIIRA***, thus requiring an extension of search. Similarly, Group VI is drawn to pharmaceutical compositions comprising an ***AIIRA*** and an OP/BMP morphogen, thus also requiring an extension of search beyond Group I. Group III-IV are drawn to stem cell therapy, thus do not share any common method steps with Group I and would require separate searches. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case methods of treatment of renal disease in mammals does not require the use of the products claimed in Group V; i.e., renal disease can be treated with other products. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group II is drawn to methods of administering an OP/BMP morphogen (or inducer or agonist thereof), and an ***AIIRA***, whereas Group V is drawn to pharmaceutical compositions comprising an ***ACEI*** and an OP/BMP morphogen, thus requiring an extensionof search. Groups III-VI are drawn to stem cell therapy, thus do not share any common method steps with Group II and would require separate searches. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case methods of treatment of renal disease in mammals does not require the use of the products claimed in Group VI; i.e., renal disease can be treated with other products. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group III is drawn methods of stem cell therapy comprising introducing renal mesenchymal progenitor cells pre-treated with an ***ACEI*** and an OP/BMP morphogen (or inducer or agonist thereof) and Group IV is drawn to methods of stem cell therapy comprising introducing renal mesenchymal progenitor cells pre-treated with an ***AIIRA*** and an OP/BMP morphogen (or inducer or agonist thereof), thus requiring an extension of search. Groups V-VI are drawn to pharmaceutical compositions and not stem cell therapy. Likewise, invention IV, which is drawn to stem cell therapy is not related to inventions V-VI, which are drawn to pharmaceutical compositions. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs,

modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, each Group is drawn to different pharmaceutical compositions, because although they share the common ingredient of an OP/BMP morphogen; Group V comprises an ***ACEI*** and Group VI comprises an ***AIIRA***, thus requiring an extension of search.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct **species: OP/BMP MORPHOGEN**. The species are independent or distinct because they are different proteins; success with one does not guarantee success with another.

IDENTITY OF OP/BMP MORPHOGEN

I-A. SEQ ID NO: 3

I-B. A fusion polypeptide comprising a C-terminal cysteine domain and a second polypeptide selected from polypeptides recited in claim 61.

I-C. SEQ ID NO: 2

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 56 and 57 are examples of generic claims.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct **sub-species: SECOND POLYPEPTIDE OF SPECIES I-B**. The sub-species are independent or distinct because the identity of the second polypeptide in the fusion protein makes the protein distinct; success with one particular fusion protein does not guarantee success with another.

SECOND POLYPEPTIDE OF SPECIES I-B

II-A. OP-1

II-B. OP-2

II-C. OP-3

II-D. BMP2

II-E. BMP3

II-F. BMP4

II-G. BMP5

II-H. BMP6

II-I. BMP9

Applicant is required under 35 U.S.C. 121 to elect a single disclosed sub-species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no examples of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the sub-species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional sub-species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected sub-species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C Kemmerer

Christina Borgeest, Ph.D.

ELIZABETH KEMMERER
PRIMARY EXAMINER